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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,689	04/15/2005	Takashi Kenmoku	03500.017653	1818

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FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER

LILLING, HERBERT J

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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02/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,689

Applicant(s)

KENMOKU ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 4-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Receipt is acknowledged of a response filed December 20, 2007 to an Office action filed September 20, 2007.

2. Claims 1-29 remain pending in this application.

Claims 4-29 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 13, 2007.

Claims 1-3 are drawn to the elected invention.

3. In accordance with this Tech Center Policy based on above restriction containing product claims and process claims, this Examiner will rejoin any non-elected process claims upon the election of a product claim which is subsequently is found allowable in view of the following guidelines:

F.P.: Ochiai/Brouwer Rejoinder form paragraph

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable; withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The arguments submitted have been deemed not to be persuasive and all of the rejections have been maintained as follows:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for examples for preparing copolymeric products having units of monomeric units, does not reasonably provide enablement for the claimed products having specific structure(s) containing the specific units in specific ratios. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and practice the invention commensurate in scope with these claims.

Applicant has failed to provide evidence of isolating a single product having a specific structure and properties but only mixtures of polymers having monomeric units having an average molecular weight for the mixture of different polymers in the mixture. Applicant has failed to provide a purified product having specific properties, which includes molecular weight (MW), B.P.; M.P. or any other intrinsic properties.

Applicant has argued the following:

"The specification sets forth a process for forming the claimed copolymers, including the disclosure of the microorganisms used to produce them, the media and the substrate. Applicants submit that once the monomer units are produced, a person skilled in the art would readily know how to polymerize these monomers to form copolymers. What is more, there is no requirement for a patent application to provide an example of isolating a claimed product. The enablement requirement is satisfied if a person skilled in the art would be able to practice the invention without undue experimentation based not only on the disclosure in the specification but the knowledge in the art. Applicants submit that the disclosure of a process of forming the monomers of the copolymer is sufficient for a skilled artisan to form the claimed copolymer without undue experimentation. For these reasons, Applicants respectfully request withdrawal of the § 112 rejection."

The elected claims are drawn to a "copolymer" product which product is required to know the structure of the claimed product for any proper search and examination of the claimed products. It has been denoted that the language of the claims must make it clear what subject matter the claims encompass to adequately delineate their "metes and bounds" and the claims must be clearly indicated as to the "structure of the product copolymer(s) before the claimed subject matter can properly be compared to the prior art, it is essential to know what the claims do in fact cover. An examination of units within the scope of the copolymer(s) does not define the claimed copolymer(s). Applicant has not indicated the product of the copolymer which includes the complete structure within the copolymer for the claimed product, thus the only alternative is that Applicant have to go to the Board of Appeals since this Examiner will not enter any amendments that would require any additional search for a claimed copolymer product per se based on the inadequate subject matter.

Claims 1-3 fail to adequately describe the copolymer per se.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -
(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351 (a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21 (2) of such treaty in the English language.

Claims 1-3 stand rejected under 35 U.S.C...102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Imamura et al U.S. 7,045,321 alone or further in view of Kenmoku et al U.S. 6,869,782. Imamura et. al., teaches the preparation of formula 1, which polyhydroxyalkanoate has been prepared by essentially the same procedure as the instant specification examples with the same microorganism with substrate that yields monomeric units as indicated in formulas 1, 23 and 28 which formulations prepared are mixture of various monomeric units that includes the claimed units as noted in the previous office action.

In view of the essentially same procedure yielding monomeric units as required by the claimed products, one would reasonably expect that the reference products produced by the same microorganism would also yield the same monomeric units in the compositions of Inamura et al, based on the following court decisions:

It is well settled that if a reference reasonably teaches a product which is identical or substantially identical or are produce by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not inherently possess the characteristics of his claimed product. A rationale given for shifting the burden of going forward to applicant is that the PTO does not possess the facilities to manufacture or to obtain and compare prior art products, see In re Brown, 459 F.2d 531, 535,173 USPQ 685, 688 (CCPA 1972); In re Best, 562 F.2d 1252, 1255,195 USPQ 430, 433-434 (CCPA 1977).

Applicant prepared the product by a procedure which involved not the copolymerization of the monomeric units but by the culturing of a microorganism in the presence of a substrate which microorganism produced unknown ranges of polymeric mixtures which was obtained by NMR evaluations. The instant specification had no examples for the polymerization of the monomeric units by chemical synthesis based on a molar ratio of the monomeric units which alleged proportions of three units yielded an unreasonable 101% for the ratios of the peak areas.

6. Claims 1-3 are rejected under 35 U.S.C. 103(a) as obvious over Imamura et al U.S. 7,045,321 alone or further in view of Kenmoku et al U.S. 6,869,782. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness:

Further in view of *KSR Inter Co v. Teleflex Inc* 550 US, 82USPQ2d 1385 (2007). The issue is that the copolymers as taught by Imamura et al differ only in the analog bonding which copolymeric products are prepared by the same method to form similar products having the same properties. Thus, the specific phenoxy component unit would have been prima facie obvious to one of ordinary skilled in the art in view of US 7,045,321 further in view of Imamura et al to substitute the phenoxy unit for that of formula 1 as taught in US 7,045,321 since it would be reasonable to expect to obtain the same properties absent a showing to the contrary.

The copolymeric products are not patentable over the references since one skilled in the art could have combined by the same known methods with no change in their respective functions and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is also noted that the claims to a copolymer that is prima facie obvious based on the primary reference having the primary unit of unsaturation which properties are intrinsic to the copolymer of the reference will not be considered to be patentable due to the alleged improvements since patentability of old or obvious products with alleged inherent or intrinsic properties not disclosed does not impart patentability for the old products.

Based on the disclosure of the references cited Imamura et al and Kenmoku et al, one skilled in the art would be able to copolymerize any two monomeric units to form a mixture of the polymers which renders the instant claims unobvious based on KSR. However, the instant specification does not teach the copolymerization of any two monomeric units but the polymerization of unknown structural mixture products having different molecular weights. Thus, the claimed products based on the disclosure would have been prima facie obvious even if there are no examples in the prior art cited but based on common knowledge and known reactions pertaining to monomeric units.

7. No claim is allowed.

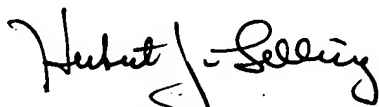
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is 571-273-8300, or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1657
January 31, 2008

A handwritten signature in black ink, appearing to read "Herbert J. Lilling". The signature is fluid and cursive, with the first name "Herbert" and last name "Lilling" clearly distinguishable.

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657